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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,526	02/09/2001	Imre Kovesdi	206060	8376

23460 7590 02/12/2004  
LEYDIG VOIT & MAYER, LTD  
TWO PRUDENTIAL PLAZA, SUITE 4900  
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EXAMINER

TRAN, MY CHAU T

ART UNIT PAPER NUMBER

1639

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/780,526	<b>Applicant(s)</b> KOVESDI ET AL.	
	<b>Examiner</b> My-Chau T. Tran	<b>Art Unit</b> 1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 April 2003.  
2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-53 is/are pending in the application.  
4a) Of the above claim(s) 7,8,10,11 and 13-53 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-6,9 and 12 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 09 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                                        |                                                                                         |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>see attached pg.3</u> . | 6) <input type="checkbox"/> Other: _____                                                |

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### **DETAILED ACTION**

**Note:** The examiner for your application in the PTO has changed. However, the Group and/or Art Unit location of your application in the PTO is remained the same, which is Group Art Unit 1639.

#### ***Election/Restrictions***

1. Applicant's election with traverse of Group I (Claims 1-12) filed on 4/9/03 is acknowledged. The traversal is on the ground(s) that Group II (Claims 13-15) be rejoined with Group I because of overlapping search and consideration. This is not found persuasive because these inventions are distinct for the reasons given in the Office Action mailed 1/13/03 (e.g. the library of Invention I can be used to screen for antigen-antibody interactions without comparing the activity of the gene products encoded by the library with activity of other gene products) and the examination requirement is ***not*** co-extensive so that the search and examination for one invention would ***not encompass*** the limitations of the other inventions thus resulting in divergence of the search and examination evaluations. Thus, Group II (Claims 13-15) is not rejoined with Group I (Claims 1-12).

The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 13-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 4/9/03.

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3. Applicant's species election with traverse filed on 4/9/03 is acknowledged. Applicant has elected the following species for the elected invention (Claims 1-12):

- a. A species of first gene product: vascular endothelial growth factor (VEGF).
- b. A species of second gene product: proteins.

Because applicant did not distinctly and specifically point out the supposed errors in the species restriction requirement, the requirement is still deemed proper and is therefore made **FINAL**.

4. Claims 7-8, and 10-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4/9/03.

#### ***Information Disclosure Statement***

5. The information disclosure statements (IDS) submitted by applicant filed on 3/14/01, 7/2/01, and 9/4/01 are acknowledged and considered.

#### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-2, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al. (US Patent 6,001,557).

Wilson et al. disclose adenoviral vector construct wherein the vector comprises a selected transgene under control of a selected promoter (first gene product) and other conventional vector/plasmid regulatory components (second gene product) (col.2, lines 36-51; col. 5, lines 17-31). Therefore, the adenoviral vector construct of Wilson et al. anticipates the presently claimed invention

8. Claims 1-2, and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by M<sup>c</sup>Vey et al. (US Patent 6,440,728 B1).

The applied reference has common inventors (Duncan L. M<sup>c</sup>Vey, Douglas E. Brough, and Imre Kovesdi) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed

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but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

M<sup>c</sup>Vey et al. disclose an adenoviral vector construct wherein the vector comprises a growth discrimination gene (first gene product) and a negative selection gene (second gene product) (col. 2, lines 6-33; col. 23, line 59 to col. 24, line 10). These genes are under control of separate regulatory elements (col. 2, lines 29-33). Therefore, the adenoviral vector construct of M<sup>c</sup>Vey et al. anticipates the presently claimed invention.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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11. Claims 1-6, 9, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US Patent 6,001,557).

Wilson et al. disclose adenoviral vector construct wherein the vector comprises a selected transgene under control of a selected promoter (first gene product) and other conventional vector/plasmid regulatory components (second gene product) (col.2, lines 36-51; col. 5, lines 17-31).

The features of remaining dependent claims are either inherently present in the compositions (e.g. type of promoter), or constitute obvious variations in parameters which are routinely modified in the art (e.g. type of gene product), and which have not been described as critical to the practice of the invention.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00 -2:30; Tuesday-Thursday: 7:30-5:00; and Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct  
February 9, 2004

  
PADMASHRI PONNALURI  
PRIMARY EXAMINER